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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,650	09/29/2000	Ursula Busse	1619.0080001/SRL/TBB	1706

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GOUDREAU GAGE DUBUC
800 PLACE VICTORIA, SUITE 3400
MONTREAL, QUEBEC, H4Z 1E9
CANADA

EXAMINER
DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/675,650	BUSSE ET AL.	
	Examiner	Art Unit	
	Natalie A. Davis	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7-11 and 13-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 9-12, drawn to a nucleic acid encoding PCA3 mRNA and a kit, classified in class 536, subclass 23.1.

II. Claims 7-8, drawn to a method of detecting PCA3 mRNA in a sample using a nucleic acid, classified in class 435, subclass 6.

III. Claims 13-14, drawn to a PCA3 polypeptide, classified in class 530, subclass 350.

IV. Claim 15, 17, and 18 drawn to a PCA3 antibody, and hybridoma kit, classified in class 424, subclass 9.1.

V. Claim 16, drawn to a method of detecting PCA3 mRNA in a sample using a nucleic acid, classified in class 435, subclass 7.1

VI. Claim 19, drawn to a method of treating prostate cancer, classified in class 514, subclass 44.

VII. Claim 20-23, drawn to a method of diagnosing, staging, and assessing the status of prostate cancer, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, III, and IV (products) and II and V-VII (methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I, III, and IV may be used for a number of different processes that are very much unrelated. For example, protein agent of Group I may not only be used in the method of Group V, but may also be used for used for affinity purification or antibody purification.

3. The products of Groups I, III, and IV are drawn to structurally and functionally different molecules with different immunological properties, each invention requires different reagents and steps to make and characterize it.

4. The methods of Groups II and V-VII relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and/or require different search strategies, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. A voicemail message was left for Attorney Ludwig on 23 October 2001 requiring an election to the restriction requirement as indicated above. A voicemail message was received from Attorney Ludwig on 10 December 2001, wherein a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6 and 9-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-8 and 13-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. It is indefinite in claims 1 and 6 as to the metes and bounds of "long." There is no clear indication as to what constitutes a "long" sequence.

11. Claims 3 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO: 1, 3, and 4, or a full complement, does not reasonably provide enablement for a nucleic acid molecule that is at least 90% identical to SEQ ID NO: 1 and 3 and a complement thereof or a nucleic acid sequence that is complementary to at least 10 nucleotides SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

12. Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There are many nucleic acid molecules that may or may not perform the same biological functions and the specification does not give any guidance to which molecules having at least 90% sequence identity to SEQ ID NO: 1 and 3, or a complement thereof and a sequence that is complementary to at least 10 nucleotides SEQ ID NO: 4, will exhibit the biological activities as the claimed, or any guidance as to which regions of the sequence must be preserved so the molecule will function as claimed. Thus, it would be an undue burden to one of ordinary skill in the art to assay for claimed sequences, which are capable of functioning as contemplated. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any nucleic acid molecule that is at least 90% sequence identity to SEQ ID NO: 1 and 3, or a complement thereof and a sequence that is complementary to at least 10 nucleotides SEQ ID NO: 4 and applicant has not enabled all of these types of modifications because it has not been shown that these molecules are capable of functioning as that which is being disclosed.

14. Articles by Burgess et al., Lazar et al., and Bowie et al. are cited to in order to establish the general state of the art on the predictability of determining protein function based on

sequence identity. Burgess et al. (J of Cell Bio. 111:2129-2138, 1990), state that conservative replacement of a single "lysine" reside at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (Lazar et al. Molecular and Cellular Biology 8:1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Furthermore, the specification fails to teach what deletions, truncations, substitutions and mutations of the disclosed sequence can be tolerated that will allow the protein to function as claimed. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with reasonable expectation of success are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or no substitutions. Residues that are directly involved in protein functions such as binding will certainly be among the most conserved (Bowie et al. Science, 247:1306-1310, 1990, p. 1306, col.2). Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to use any and all molecules with sequence similarity to the amino acid sequence shown in SEQ ID NO. 3. Therefore, in view of the lack of predictability of the prior art, the breadth of the claims and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

16. Claims 1-3, 5, and 9-12 rejected under 35 U.S.C. 102(e) as being anticipated by Bussemakers, (1998, WO 9845420-A1).

17. Bussemakers disclose the PCA3 antigen (Accession AAW79736) as set forth in SEQ ID NO: 3. Bussemakers further disclose, methods of detecting nucleic acids, kits, cells containing recombinant nucleic acid molecules comprising 5' to 3' promoters effective to initiate transcription in a host cell, and non-human organisms that contain the recombinant nucleic acids. It is inherent that Bussemakers disclose a complement to SEQ ID NO: 4 as probes and primers are used in the detection of PCA3 molecules. Accordingly, Bussemakers anticipates claims 1-2, 5, and 9-12 as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.
December 20, 2001

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600